

Claims

1. An albumin fusion protein comprising IL-11, or a fragment or variant thereof, and albumin, or a fragment or variant thereof.
- 5 2. The albumin fusion protein of claim 1, wherein the IL-11 is human IL-11.
3. An albumin fusion protein according to Claim 1 or 2, comprising an albumin fused to IL-11.
- 10 4. The albumin fusion protein of any preceding claim, wherein the IL-11 is human IL-11.
5. The albumin fusion protein of claim 1 wherein the albumin has the ability to prolong the *in vivo* half-life of IL-11, or a fragment or variant thereof, compared 15 to the *in vivo* half-life of IL-11, or a fragment or variant thereof, in an unfused state.
6. The protein of claim 5, whereby the half-life of said albumin-fused IL-11 is extended at least 5-fold over the half-life of the IL-11 lacking the linked 20 albumin.
7. The protein of claim 6, whereby the half-life of said albumin-fused IL-11 is extended at least 10-fold over the half-life of the IL-11 lacking the linked albumin.
- 25 8. The protein of claim 7 whereby the half-life of said albumin-fused IL-11 is extended at least 50-fold over the half-life of the IL-11 lacking the linked albumin.
9. The albumin fusion protein of claim 1 wherein IL-11, or a fragment or 30 variant thereof, is fused to the N-terminus of albumin, or the N-terminus of the fragment or variant of albumin.

10. The albumin fusion protein of claim 1 wherein IL-11, or a fragment or variant thereof, is fused to the C-terminus of albumin, or the C-terminus of the fragment or variant of albumin.
- 5 11. The albumin fusion protein of claim 1 wherein IL-11, or a fragment or variant thereof, is fused to an internal region of albumin, or an internal region of a fragment or variant of albumin.
- 10 12. The albumin fusion protein of claim 1 wherein IL-11, or a fragment or variant thereof, is separated from the albumin or the fragment or variant of albumin by a linker.
- 15 13. The albumin fusion protein of any preceding claim wherein the *in vitro* biological activity of the IL-11, or fragment or variant thereof, fused to albumin, or fragment or variant thereof, is greater than the *in vitro* biological activity IL-11, or fragment or variant thereof, in an unfused state.
- 20 14. The albumin fusion protein of any preceding claim wherein the *in vivo* biological activity of IL-11, or fragment or variant thereof, fused to albumin, or fragment or variant thereof, is greater than the *in vivo* biological activity of IL-11, or fragment or variant thereof, in an unfused state.
15. A nucleic acid molecule comprising a polynucleotide sequence encoding the albumin fusion protein of any preceding claim.
- 25 16. A vector comprising the nucleic acid molecule of claim 15.
17. A host cell containing the nucleic acid molecule of claim 15.
- 30 18. A method for manufacturing an albumin fusion protein of any of claims 1-14, the method comprising (a) providing a nucleic acid comprising a nucleotide sequence encoding the albumin fusion protein expressible in a cell or organism;

(b) expressing the nucleic acid in the cell or organism to form an albumin fusion protein; and (c) purifying the albumin fusion protein.

19. The method of claim 18 wherein the albumin fusion protein is expressed in
5 a yeast.

20. The method of Claim 19 wherein the yeast is glycosylation deficient.

21. The method of claim 19 wherein the yeast is glycosylation competent.

10 22. The method of Claim 18 wherein the albumin fusion protein is expressed
in a mammalian cell in cell culture.

23. A composition comprising the albumin fusion protein of any one of claims
15 1-14 and a carrier.

24. A pharmaceutical composition comprising an effective amount of the
albumin fusion protein of any one of claims 1-14 and a pharmaceutically
acceptable carrier or excipient.

20 25. A method for minimizing a side effect associated with the treatment of a
mammal with IL-11 comprising administering an albumin-fused IL-11 to said
mammal.

25 26 A method according to Claim 25 wherein the mammal is suffering from a
bowel disorder and the side effect is weight loss, rectal bleeding or diarrhoea.

27 A method of increasing weight in a mammal suffering from a bowel disease
causing weight loss, the method comprising administering an albumin-fused IL-11
30 to said mammal.

28. A method of treating a disease or disorder in a patient, comprising the step of administering an effective amount of the albumin fusion protein of any of claims 1-14.

5 29. A method of treating a patient, comprising the step of administering an effective amount of the albumin fusion protein of any of claims 1-14.

10 30. A method of extending the *in vivo* half-life of IL-11, or a fragment or variant thereof, comprising the step of fusing IL-11, or fragment or variant thereof, to albumin or a fragment or variant of albumin sufficient to extend the *in vivo* half-life of IL-11, or fragment or variant thereof, compared to the *in vivo* half-life of IL-11, or fragment or variant thereof, in an unfused state.

15 31. A method for extending the half-life of IL-11 in a mammal, the method comprising linking said IL-11 to an albumin to form an albumin-fused IL-11 and administering said albumin-fused IL-11 to said mammal, whereby the half-life of said albumin-fused IL-11 is extended at least 2-fold over the half-life of IL-11 lacking the linked albumin.

20 32. A method for preventing or treating thrombocytopenia in a mammal, the method comprising administering an albumin-fused IL-11 to said mammal.

25 33. A method for minimizing a side effect associated with the treatment of a mammal with IL-11, the method comprising administering an albumin-fused IL-11 to said mammal.